RESEARCH and analyses

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## HIGHLIGHTS

- In **83%** of cases, there are no specific requirements in terms of education in research ethics for clinical investigators.
- Similarly, **69%** of research centres have no specific requirements for their clinical investigators (physicians, other health professionals or Ph.D. holders) in terms of education in research ethics.
- The **respondents unanimously** consider it advisable for clinical investigators to be educated in research ethics.
- Training in research ethics is dispensed either through spot training (professional development, workshops and seminars) with **48%** support, or through instructional software **(32%)**.
- Most research ethics boards **(78%)** do not require ethics training as a prerequisite for new members. Once appointed, they must, however, in **71%** of cases, receive ethics training.

## RESEARCH ETHICS

# Survey on ethics education in FRSQ research centres*

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Further to tabling of the Morin Report and in the wake of the research ethics forum held in October 2005, the FRSQ instituted an advisory committee on education in research ethics tasked with making specific recommendations regarding ethics education formats for use in research centres and ethics education criteria for eligibility for FRSQ programs.

To order to establish which practices are currently used by universities and hospital centres in terms of education in research ethics, the committee conduced a survey of the chairs of boards of directors, directors of research centres, chairs of research ethics boards, and deans of faculties of medicine, pharmacy, dentistry and nursing.

In addition to profiling the current situation in education in research ethics, the survey also gleaned the opinions and recommendations of the main stakeholders in the field, with a view to better identifying their needs.

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**Currently, specific qualifications with regard to research ethics are rarely required.**

- According to **83%** of chairs of boards of directors, their institutions have are no particular requirements in terms of education in research ethics in order for clinical investigators to be granted research privileges.
- The same holds true for **69%** of the directors of research centres, who reported they had are no particular requirements in terms education in research ethics for clinical investigators (physicians, other health professionals, or Ph.D. holders).
- **62%** of directors of research centres said they had are no particular requirements in terms of education in research ethics for research assistants.
- The few respondents who reported having specific requirements identified the following six elements:
  - Training in Standard Operating Procedures (SOPs)
  - Training in Good Clinical Practice (GCP), Consolidated Guideline – International Conference on Harmonization
  - University course in research ethics
  - Training in the research ethics board's institutional procedures and requirements
  - Knowledge of the research ethics board's rules of operation
  - Knowledge of the Tri-Council Policy Statement.

**Ethics education of members of research ethics boards**

- By definition, research ethics boards are central to the process of evaluating research project ethics. Adequate training in research ethics for its members therefore seems advisable in order to ensure compliance with research ethics standards.
- However, the answers from research ethics board chairs show that in **78%** of cases, the members of the research ethics board are not required to have training in research ethics before becoming a member. Once appointed, they must, in **71%** of cases, obtain such training.

**All respondents said that education in research ethics was advisable.**

- **All stakeholders** answered yes when asked: "Do you think it would advisable for clinical investigators and their assistants to be educated in research ethics?"
- As for making this training mandatory, **78%** of respondents felt it should be compulsory for clinical investigators (physicians, other health professionals, or Ph.D. holders), while **70%** felt it should compulsory for research assistants as well.
- As indicated in Table 1, respondents seem to prefer spot training. When combined, professional development, workshops and seminars received **48%** of support. Types of training with more flexible schedules ranked second with respondents. The Ministère de la Santé et des Services sociaux (MSSS) courseware and that of the three federal granting agencies together accounted for **32%**. Lastly, university courses had the weakest support, with only **20%**. In the case of lectures, support fell to **9%**.

**Factors to focus on in education in research ethics**

- Ethics experts feel that training that is less operational and that is based on research ethics principles is highly advisable. The purpose of the training should be to make ethical reasoning standard practice in the everyday process of research.
- Respondents identified a number of training needs more connected to the practical aspects of research:
  - Guiding principles in research ethics
  - Researchers' and research assistants' obligations and responsibilities
  - Rules governing protection and legal aspects
  - Operating rules of the institution's research ethics board

- Drafting of consent forms and explanations regarding the form
- Standard Operational Procedures (SOPs)

- They also identified training needs with regard to research norms, rules and standards:
  - Content of the Tri-Council Policy Statement
  - FRSQ's Advisory Committee on Research Ethics and Scientific Integrity
  - Standards governing management of databanks and tissue banks
  - Good Clinical Practice (GCP), Consolidated Guideline – International Conference on Harmonization
  - *Food and Drug Administration* (FDA- United States) standards
  - Main provisions of the *Food and Drugs Act*

**Table 1 – Types of training recommended by the respondents***

| | |
|---|---|
| **University course** | |
| • Lectures | 9% |
| • On-line | 11% |
| **Other kinds of training** | |
| • Ministère de la Santé et des Services sociaux software | 17% |
| • Tri-Council Policy Statement tutorial | 15% |
| • Professional development activities | 15% |
| • Workshops | 18% |
| • Seminars | 15% |

* Respondents were asked to identify the kinds of research ethics training they felt were the most relevant. They were also asked to identify a number of choices for the three categories of stakeholders: clinical investigators (physicians, other health professionals, or Ph.D. holders), research assistants, and members of research ethics boards.

## Methodological note

The findings presented in this document are taken from a questionnaire-survey mailed in early summer 2006. In all, 73 persons were invited to participate and 51 completed questionnaires were returned, for a total participation rate of 70%. Participation rates were satisfactory for each category of respondent: chairs of boards of directors (71%), directors of research centres (68%), chairs of research ethics boards (86%), and deans of faculties of medicine, pharmacy, dentistry and nursing (50%).